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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,245	06/24/2002	Johan - Valentin Kahl	GRUNP118	9295

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IP STRATEGIES
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SUITE I
ASHEVILLE, NC 28801

EXAMINER	
BARTON, JEFFREY THOMAS	
ART UNIT	**PAPER NUMBER**
1753	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,245	KAHL ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Barton	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *47-66* is/are allowed.

6)☒ Claim(s) *67-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 9 December 2005 does not place the application in condition for allowance.

Status of Objections and Rejections Pending Since the Office Action of 19 September 2005

2. The rejection of claims 82-84 under 35 U.S.C. §112(1) is obviated due to cancellation of the claims.

3. All other rejections are withdrawn due to Applicant's amendment.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 67-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 67 recites the limitation that the membrane is swelled "by the addition of only at least one of water and a buffer solution." This is unclear because the word "only" implies the addition of one item, while "at least one of" leaves the claim open to the addition of multiple (i.e. two) items.

In addition, claim 69 requires the membrane to include "amphiphilic macromolecules", which would appear to contradict the membrane being "composed only of lipids".

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. In the following rejections, undue weight cannot be given to the limitation "swelled from a dried up state by the addition of only at least one of water and a buffer solution." This limitation is drawn to a product formed by a process. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) In this case, no difference between a newly

made membrane (i.e. Groves, Boxer) and the claimed rehydrated membrane is apparent. Therefore, this limitation cannot be relied upon for patentability.

8. Claims 67, 69-72, 75-78, 80, and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by Groves et al.

Regarding claims 67, 69-72, and 75, Groves et al disclose a microchannel electrophoresis chamber (Figure 2 and caption; the thickness of the membrane/fluid layer is disclosed as 10-50 micrometers; since the volume defined between the two coverslips has at least one micrometer-scale dimension, it reads on a "microchannel", broadly defined) comprising a channel having a bottom surface including a substrate-supported fluid lipid membrane composed only of lipids. (Page 2717, First 9 lines of the "Supported bilayers" section; specific to claim 69, the membrane is disclosed as being modified to include tethered antibodies, which are amphiphilic macromolecules (e.g. Figure 3))

Regarding claim 76, Groves et al disclose the microchannel chamber being connected to an electrode assembly. (Figure 2)

Regarding claim 77, this channel is 10 mm wide.

Regarding claim 78, the channel depth is disclosed as 10-50 microns. (Figure 2 caption)

Regarding claims 80 and 81, the electrodes pictured in Figure 2a are on the longitudinal ends of the channel, and extend longitudinally in the direction of the channel from either end.

9. Claims 67, 69, 70, and 72-80 are rejected under 35 U.S.C. 102(e) as being anticipated by Boxer et al.

Regarding claims 67, 69, 70, 72, and 75, Boxer et al disclose lipid bilayer membranes that are supported on glass coverslips (Column 7, lines 20-40), with barriers (28) that divide the membrane and can extend above the substrate to a height of several micrometers. (Column 5, lines 59-64) The areas between these barriers can thus be called "microchannels", given this microscale dimension. Proteins are optionally included in the bilayer, which reads on claim 69. (Column 7, lines 38-40)

Regarding claims 73 and 74, Boxer et al disclose the support comprising PMMA. (Column 10, lines 4-11)

Regarding claim 76, Boxer et al disclose the microchannel chamber being connected to an electrode assembly. (e.g. Figure 5)

Regarding claim 77, the supports (and therefore channels) are disclosed as having dimensions as low as 5 mm per side. (Column 5, lines 41-43)

Regarding claim 78, the disclosed bilayer and aqueous film thickness would result in a channel of this depth. (Column 5, lines 50-64)

Regarding claim 79, Boxer et al disclose two-dimensional arrays of membrane sections, which could be called channels. (e.g. Figure 2, Column 8, lines 43-52)

Regarding claim 80, the electrodes pictured in Figure 5 are on the longitudinal ends of the channel.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Groves et al in view of Bailey et al.

Groves et al disclose a device as described above in addressing claim 67.

Groves et al do not explicitly disclose a membrane comprising cationic lipids.

Bailey et al disclose preparation of liposomes comprising bilayers including cationic lipids. (Abstract)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Boxer et al and Goodrich et al by using bilayers comprising cationic lipids, as taught by Bailey et al, because Bailey et al teach their ability to form bilayers and the function of the cationic lipid in promoting liposome fusion.

14. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boxer et al in view of Bailey et al.

The reasoning for this rejection parallels that given above in paragraph 13.

Allowable Subject Matter

15. Claims 47-66 have been allowed, for reasons given in the Office Action of 19 September 2005.

Response to Arguments

16. Applicant's arguments filed 9 December 2005 have been fully considered but they are not persuasive. Applicant's arguments hinge entirely on the limitation that the membrane is "swelled from a dried up state by the addition of only at least one of water and a buffer solution." As indicated above, the Examiner considers this limitation to be indefinite. In addition, as also indicated above, since the limitation is directed to a product formed by a process, it cannot be the basis for patentability where no structural difference is defined by the process. Therefore, the arguments cannot be persuasive.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB
15 February 2006

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